

Health and Human Services

370.301

(c) *Indian organization* means the governing body of any Indian Tribe, or entity established or recognized by such governing body, in accordance with the Indian Financing Act of 1974 (88 Stat. 77, 25 U.S.C. 1451).

(d) *Indian-owned economic enterprise* means any Indian-owned commercial, industrial, or business activity established or organized for the purpose of profit, provided that such Indian ownership shall constitute not less than 51 percent of the enterprise, and the ownership shall encompass active operation and control of the enterprise.

(e) *Indian reservation* includes Indian reservations, public domain Indian allotments, former Indian reservations in Oklahoma, and land held by incorporated Native groups, regional corporations, and village corporations under the provisions of the Alaska Native Claims Settlement Act (85 Stat. 688, 43 U.S.C. 1601 *et seq.*)

(f) *On or near an Indian Reservation* means on a reservation or reservations or within that area surrounding an Indian reservation(s) where a person seeking employment could reasonably be expected to commute to and from in the course of a work day.

370.204 Compliance enforcement.

(a) The contracting activity shall conduct periodic reviews to ensure contractor compliance with the requirements of the clauses in 352.270-2 and 352.270-3. The Indian Tribe(s) concerned may assist in the conduct of these reviews.

(b) The Contracting Officer shall promptly investigate and resolve complaints of noncompliance with the requirements of the clauses in 352.270-2 and 352.270-3 that are filed in writing with the contracting activity.

370.205 Tribal preference requirements.

(a) When the contractor will perform work under a contract on an Indian reservation, the Contracting Officer may supplement the clause in 352.270-3 by adding specific Indian preference requirements of the Tribe on whose reservation the work is to be performed. The contracting activity and the Tribe shall jointly develop supplemental requirements for the contract. Supplemental

preference requirements shall represent a further implementation of the requirements of section 7(b) of Public Law 93-638 and require the approval of the affected program director and OGC-GLD, or a regional attorney, before the Contracting Officer adds them to a solicitation and resultant contract. Any supplemental preference requirements the Contracting Officer adds to the clause in 352.270-3 shall also be part of the solicitation and clearly identified, to ensure uniform understanding of the additional requirements by all prospective bidders or offerors.

(b) Nothing in this part shall preclude tribes from independently developing and enforcing their own Tribal preference requirements. Such independently developed Tribal preference requirements shall not, except as provided in paragraph (a) of this section, become a requirement in contracts covered under this 370.2, and shall not conflict with any Federal statutory or regulatory requirement concerning the award and administration of contracts.

Subpart 370.3—Acquisitions Involving Human Subjects

370.300 Scope of subpart.

This subpart applies to all R & D activities involving human subjects conducted under contract—see 45 CFR 46.102(d) and (f).

370.301 Policy.

It is HHS policy that the Contracting Officer shall not award a contract involving human subjects until a prospective contractor has provided acceptable assurance that the activity will be subject to initial and continuing review by an appropriate Institutional Review Board (IRB) as described in HHS regulations at 45 CFR 46.103. The Contracting Officer shall require an applicable Federal-wide assurance (FWA), approved by the HHS Office for Human Research Protections (OHRP), of each contractor, subcontractor, or cooperating institution having responsibility for human subjects involved in performance of a contract. OHRP is responsible for negotiating assurances covering all HHS-supported or HHS-conducted activities involving